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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/597,395	07/24/2006	Yulin Ren	27211/04220	1395

24024 7590 06/23/2009
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EXAMINER

KRISHNAN, GANAPATHY

ART UNIT	PAPER NUMBER
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1623

NOTIFICATION DATE	DELIVERY MODE
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06/23/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/597,395	Applicant(s) REN ET AL.	
	Examiner Ganapathy Krishnan	Art Unit 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 June 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Specification

The first page of the WIPO document filed 6/24/2008, which has an abstract, has also been used as the abstract sheet in the instant specification. This is not acceptable if the instant claims are determined to be allowable at a later stage. The Office requires the abstract to be typed on a separate sheet of paper even though applicants intend using the abstract on the WIPO document for the instant application. Hence, applicants are requested to kindly type the abstract appearing on the first page of the WIPO document (WO 2005/070943) on a separate sheet and file the same.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-25 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for separation of α -penta-O-galloyl-D-glucose and the β - anomers from a mixture containing 50% or more of the single anomer, does not reasonably provide enablement for the separation of the anomers from a mixture containing the α -, β - and analogs of PGG, does not provide enablement for separation of α -, β - and analogs of PGG in which the ring oxygen is substituted by C, N or S and does not provide enablement for separation of α -, β - and analogs of PGG in which glucose is substituted by another hexose, pentose or tetrose. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

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A conclusion of lack of enablement means that, based on the evidence regarding each of the factors below, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation.

Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApl 1986) at 547 the court recited eight factors: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

All of the *Wands* factors have been considered with regard to the instant claims, with the most relevant factors discussed below.

Nature of the invention

The invention is drawn to a method of separation of separation of α - and β -PGG and analogs of PGG and making single crystals of the same.

The state of the prior art

According to Ault (Techniques and Experiments for Organic Chemistry, 1987, pages 44-46) crystallization of a solid from a solvent depends on the fact that different substances are soluble to differing extents in various solvents (page 44, last paragraph). There is no way to know which solvent will work best. Even if solvents are suggested in the literature they may not be useful if different impurities are involved and quite often several solvents must be tried (page

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45, section 8.1). This means that given the solubility differences, which may or may not be similar, and the amount and type of impurities present, especially in the instant case, the type of sugar ring and the analog, it is difficult to predict if crystallization would occur at all.

The predictability or unpredictability of the art

Based on the state of art above it is highly unpredictable that anomers could be separated by selective crystallization from a given solvent, especially analogs, hexose, pentose and tetrose, sugars wherein the ring oxygen is substituted with C, N or S. Such structural changes could alter properties like solubility.

The breadth of the claims

Claims 1 and 13 are drawn to a method of separation of α - and β -PGG and analogs of PGG. The term analog is broad and is seen to include several compounds. This also applies to the terms hexose, pentose and tetrose.

The amount of direction provided by the inventor

The instant specification is not seen to provide enough guidance that would allow a skilled artisan to extrapolate from the disclosure and the examples provided to enable the separation of anomers via crystallization as instantly claimed. The specification also fails to direct the skilled artisan in correlative prior art procedures which might provide the basis for using the instant method.

The presence or absence of working examples

The working examples set forth in the instant specification are drawn to crystallization of α - and β -PGG from water and acetone. Despite these examples there is little enabling disclosure for the crystallization of other analogues. Applicant has given working examples of

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the crystallization of α - and β -PGG from water and acetone only and is therefore not entitled to claim all other analogs.

The quantity of experimentation necessary

Indeed, in view of the information set forth, the instant disclosure is not seen to be sufficient to enable the separation and single crystal preparation of the α - and β - anomers of all other sugars and analogs except α - and β -PGG from water and acetone. One of ordinary skill in the art would have to carry out the process in order to determine the particular solvent and the amount to be used in the process and other process conditions such as temperature, etc.

Thus, the specification fails to provide clear and convincing evidence in sufficient support of the use of the claimed method for the separation and single crystal formation of analogs other than α - and β -PGG from water and acetone.

Genetech, 108 F.3d at 1366, states that “a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion” and “[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable”.

Therefore, in view of the *Wands* factors as discussed above, e.g., the amount of guidance provided and the predictability of the art, to practice the claimed invention herein, a person of ordinary skill in the art would have to engage in undue experimentation, with no reasonable expectation of success.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the term analogues. The recitation “analogue” in claims 1, 2 and 96 renders the claim indefinite. The recitation “analogue” is not clearly defined in the specification, and therefore does not set forth the metes and bounds of the term. The Merriam-Webster’s Online Dictionary (page 1) defines “analogue” as “a chemical compound that is structurally similar to another but differs slightly in composition”. Hence, one of ordinary skill in the art will not be able to ascertain and interpret the metes and bounds of the patent protection desired as to “analogue” herein. Thus, it is unclear and indefinite as to what all are encompassed by the term “analog”.

In claims 5, 8, 16 and 19 the terms elevated and lower are recited respectively with regard to temperature. The said terms are relative terms which render the claims indefinite. The terms are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Room temperature can also vary. Recitation of a specific temperature or a range would clarify the claim.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is

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followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claims 9 and 20 recite the broad recitation hexose, and the claims also recite glucose which is the narrower statement of the range/limitation.

Claims 24 and 27 are drawn to a method of preparing single crystal alpha- and beta-PGG respectively, which conveys the intent that the said compounds are prepared starting from simpler materials. But the claims recite steps for crystallizing the said anomers only. The recited steps are part of the process steps used in the preparation. Steps required for the actual preparation are not recited in the claims. Do applicants intend obtaining single crystals via selective recrystallization? Claim 24 is also drawn to a method of preparing single crystal of an analog of α -PGG but further recites steps involving only α -PGG.

Claims that depend from a base claim that is unclear/indefinite are also rendered unclear/indefinite and are rejected for the same reasons.

Conclusion

Claims 1-29 are rejected

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathy Krishnan whose telephone number is 571-272-0654.

The examiner can normally be reached on 8.30am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ganapathy Krishnan/
Examiner, Art Unit 1623

/Shaojia Anna Jiang/
Supervisory Patent Examiner
Art Unit 1623